

**SECTION 4**

DEC 17 2002

**SUMMARY OF SAFETY AND EFFECTIVENESS****Submitter:**

ValuMed  
1439 Live Oak Street, Suite A  
Niceville, FL 32578  
(850) 897-3321 - Phone  
(850) 897-1280 - Fax  
Thomas Cottone, President – Contact Person  
[qa@valumed.net](mailto:qa@valumed.net)

**Date Summary Prepared:** October 21, 2002

**Device Name:**

- Trade Name – Bag Decanter, Vial Decanter, Transfer Device
- Common Name – Decanting Devices
- Classification Name: I.V. Container Accessories

**Devices for Which Substantial Equivalence is Claimed:**

- Steri-Systems, Corp (K830232)
- Medical Specialty Innovations, Inc. (K961699)

**Device Description:**

The ValuMed decanting devices are one piece, injection molded hollow tubes with one or more spiked ends. Some models have a splash guard. They are sterile, single use, disposable devices.

**Intended Use of the Device:**

The ValuMed decanting devices are decanting devices intended for the aseptic dispensing of solutions from Iv containers. Each device is used as follows:

Bag Decanter:	Used to dispense fluids from flexible bags
Vial Decanter:	Used to dispense fluids from glass vials
Transfer Device:	Used to dispense fluids from small vials, or to transfer fluid from container to container.

**Substantial Equivalence:**

The ValuMed decanting devices are substantially equivalent to several other legally marketed devices in the United States. The decanting devices marketed by Steri-Systems, Corp, and the transfer devices by Medical Specialty Innovations, Inc. are substantially identical in materials, dimensions, performance, packaging, sterilization and intended use.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

DEC 17 2002

Mr. Thomas E. Cottone  
President  
ValuMed  
1439 Live Oak Street, Suite A  
Niceville, Florida 32578

Re: K023539

Trade/Device Name: Decanting Devices  
Regulation Number: 880.5440  
Regulation Name: Intravascular Administration Set  
Regulatory Class: II  
Product Code: LHI  
Dated: October 21, 2002  
Received: October 22, 2002

Dear Mr. Cottone:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

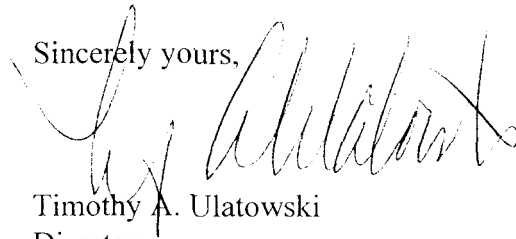
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4618. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,



Timothy A. Ulatowski

Director

Division of Anesthesiology, General Hospital,

Infection Control and Dental Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

### SECTION 3

#### STATEMENT OF INDICATIONS FOR USE

510(k) Number (if known): K 023539

Device Name: DECANTING DEVICES

#### STATEMENT OF INDICATIONS FOR USE

The ValuMed decanting devices are devices intended for the aseptic dispensing of solutions from I.V. containers. Each device is used as follows:

Bag Decanter:	Used to dispense fluids from flexible bags
Vial Decanter:	Used to dispense fluids from glass vials
Transfer Device:	Used to dispense fluids from small vials, or to transfer fluid from container to container.

*Patricia Vincent*

(Division Sign-Off)  
Division of Anesthesiology, General Hospital,  
Infection Control, Dental Devices

510(k) Number: K 023539